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THE EFFECT OF RECALL PERIOD ON CANCER PATIENTS' RATINGS OF THE SEVERITY OF MULTIPLE SYMPTOMS

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In response to the US Food and Drug Administration's concern on choice of suitable recall period for patient-reported outcomes (PRO), we examined the effects of recall on symptom severity ratings by comparing ratings made using 24-hour and 7-day recall periods of the MD Anderson Symptom Inventory (MDASI). **METHODS:** Forty-two patients at their 3rd to 8th week of chemoradiation in the Radiation Treatment Center at M.D. Anderson Cancer Center were asked to rate their symptoms using the MDASI on two separate occasions, one week apart. At the initial visit, patients were randomly assigned to rate their symptoms using either a 24-hour recall or a 7-day recall. On their next visit, patients were asked to rate their symptoms using the recall period not used at their first visit. **RESULTS:** Correlation coefficients of global symptom severity between 24-hour and 7-day recall periods were 0.89. Examining individual items, all correlation coefficients were over 0.7 except for distress (r = 0.67). The percentages of moderate to severe symptoms (5 or greater) were consistent in the 24-hour and 7-day recall periods, with no significant difference in the prevalence of moderate to severe symptoms being found between the two recall periods. Cronbach á coefficients in both 24-hour and 7-day recalls were all over 0.8. Symptoms from both recall periods were more severe for patients with poorer performance status. Among 20 patients who underwent cognitive debriefing, 70% thought the 7-day recall was "more appropriate" for answering the MDASI, but 85% did not think that recall period would influence their answers. **CONCLUSIONS:** This study demonstrated that a 7-day recall version of the MDASI has psychometric properties consistent with the 24-hour recall version, which may allow its use in future clinical trials. In addition, this study may help ease the choice of recall period when symptoms are outcome measures.

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RELATIONSHIP BETWEEN QUALITY OF LIFE AND HEALTH-RELATED MEASURES INCLUDING SYMPTOMS, BIOCHEMICAL MARKERS AND TUMOR BURDEN

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OBJECTIVES: Examine the relationship of quality of life measures in neuroendocrine tumor patients using the Norfolk QOL-NET by correlating the total questionnaire score with each of the Norfolk QOL-NET domains, with tumor burden, biochemical status and the Norfolk Carcinoid Symptom Score tool. **METHODS:** During their visits to the Neuroendocrine Unit at Eastern Virginia Medical School, 29 adult patients diagnosed with neuroendocrine tumor(s) signed the consent form and completed the Norfolk QOL-NET. Data related to current tumor burden, biochemical status and the validated Carcinoid Symptom Score was obtained from their files matching the date they completed the questionnaires. **RESULTS:** The Norfolk QOL-NET total score correlated positively with all of its domains – physical functioning ($r = 0.96$, $p < 0.0001$), depression($r = 0.73$, $p < 0.001$), gastrointestinal ($r = 0.78$, $p < 0.001$), flushing ($r = 0.62$, $p < 0.0003$), respiratory ($r = 0.65$, $p < 0.0002$), positive attitude ($r = 0.52$, $p < 0.004$), and cardiovascular ($r = 0.46$, $p < 0.012$); with the Norfolk Carcinoid Symptom Score ($r = 0.6$, $p =< .0001$); with tumor burden ($r = 0.52$, $p = 0.004$), and serotonin ($r = 0.62$, $p = 0.013$). Serotonin was the only biochemical marker that correlated positively with a poor quality of life in patients with neuroendocrine tumors. **CONCLUSIONS:** We demonstrated a strong correlation between Norfolk QOL-NET and symptoms, biochemical markers and tumor burden. Norfolk QOL-NET seems sensitive to symptom change, physical functioning, respiratory and cardiovascular disease progression or remission. Norfolk QOL-NET should be an important tool for measuring patients' perception of the burden of their disease, relating to the tumor burden and the biochemical abnormality as well as the impact of treatment modalities. The Norfolk quality of life tool may also be a useful guide in deciding changes in therapy to alter apparent health status as well as an endpoint in clinical studies.

PMC58

TEST-RETEST RELIABILITY OF THE EQ-5D VISUAL ANALOG SCALE ACROSS POPULATIONS AND CONDITIONS

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OBJECTIVES: As electronic versions of HRQL measures such as the EQ-5D become available, it is important to understand the reliability of different modes of technology. The aim of this study was to summarize the evidence of test-retest reliability for the EQ-5D visual analog scale (VAS), a scale ranging from 0 (worst imaginable health) to 100 (best imaginable health). **METHODS:** A structured literature search was conducted in MEDLINE using keywords relevant to EQ-5D, visual analog scales, and test-retest reliability. Original research studies that reported information on the test-retest reliability of the EQ-5D VAS were included. Demographic characteristics, interval between observations, and intraclass correlation coefficients (ICCs) were abstracted. **RESULTS:** Of the 25 studies that examined test-retest reliability of EQ-5D, 14 reported evidence of test-retest reliability for EQ-5D VAS. Most of the papers were studies that assessed the validity of EQ-5D for certain countries or languages (n = 5/14, 36%) or for use in patient groups / certain medical conditions (n = 7/14, 50%). The most common interval between observations was 2 weeks (n = 4/14, 29%), with analyses conducted on a subgroup of self-reported stable patients, based on self-report, in 4 studies. TRT ICCs ranged from ICC = 0.38 for Alzheimer's patients to ICC = 0.90 (95% CI: 0.88–0.92) for a methodological study conducted in Spain, with a median ICC = 0.8 across the 14 studies. Almost 80% of studies (11/14) reported ICCs above 0.7, a reliability threshold considered acceptable at the group level. **CONCLUSIONS:** EQ-5D VAS demonstrated acceptable TRT reliability in most studies of populations and medical conditions except in Alzheimer's disease, where proxies but not patients provided reproducible assessments.

PMC59

PSYCHOMETRIC ASSESSMENT OF AN INSTRUMENT TO MEASURE PATIENT SATISFACTION WITH MEDICATION THERAPY MANAGEMENT SERVICES

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OBJECTIVES: To adapt a pharmaceutical care satisfaction instrument and pilot test it to measure patient satisfaction with Medication Therapy Management (MTM) services. **METHODS:** A questionnaire was mailed to Medicare Part D beneficiaries who received face-to-face MTM services in a retail pharmacy in a southern state. The questionnaire consisted 23 questions addressing patients' perceptions, experience, and satisfaction related to MTM services. Information regarding patients' satisfaction was gathered using an instrument developed by Gourley et al. (2001) with a few modifications to make it applicable to MTM service encounter. We assessed the content validity and pre-tested the questionnaire to determine the time needed to complete and to ensure item clarity. Factor analysis using the principal component method with varimax rotation and reliability analysis using Cronbach's alpha was conducted. **RESULTS:** Of the 403 successfully mailed surveys; we received 122 useable surveys yielding a response rate of 30.27%. Sample comprised 55% females, 68% whites. Over 80% of the study participants took 5–16 unique medications daily. Factor analysis using a 0.55 cut-off for factor loading yielded four factors that accounted for 64.4% of the variance. Reliability assessment resulted in Cronbach's alpha value of 0.941 for the entire scale, 0.904 for factor 1 (Managing Medication Therapy), 0.917 for factor 2 (Patient Education), 0.910 for factor 3 (Overall Satisfaction), and 0.841 for factor 4 (Pharmacist-Patient Relationship). The overall mean score was found to be 4.5/5 indicating that the participants were satisfied with the MTM services they received. **CONCLUSIONS:** The adapted questionnaire consisted of four subscales similar to subscales found in other pharmacy satisfaction surveys. The instrument appears to be useful in measuring patient satisfaction with MTM services received in a pharmacy. Low sample size, extrapolation of results to other states and settings, and recall bias are the notable limitations associated with this study.

PMC60

DETERMINING THE MINIMALLY IMPORTANT DIFFERENCES OF FOUR PREFERENCE-BASED HEALTH INDICES: A SIMULATION APPROACH

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OBJECTIVES: To estimate the minimally important differences (MIDs) for the EQ-5D, HUI2, HUI3, and SF-6D health index scores using health-state transitions described by each instrument's health classification systems as anchors. **METHODS:** We assume that the smallest differences in health states defined by each instrument's multi-attribute health classification (MAHC) systems are associated with important differences in health preferences. Based on this assumption, the MID was defined as the difference in index score between two health states defined by each MAHC system differing in only one health dimension or attribute and by only one functional level. Thus, for each instrument, we enumerated all the theoretically possible pairs of minimally different health states and calculated the differences in index scores for those pairs of health states. **RESULTS:** Based on our definitions, the total number of pairs of minimally different health states is 405 for the EQ-5D, 127,600 for the HUI2, 6,382,800 for the HUI3, and 86,700 for the SF-6D. The mean (standard deviation) MID estimate was 0.040 (0.026) for the EQ-5D (US algorithm), 0.082 (0.032) for the EQ-5D (UK algorithm), 0.045 (0.039) for the HUI2, 0.032 (0.027) for the HUI3, and 0.027 (0.028) for the SF-6D. The effect sizes corresponding to these MID estimates range from 0.19 to 0.28. In general, these MID estimates are quite comparable to those estimated using other anchor-based methods. **CONCLUSIONS:** This new approach to estimating the MIDs of four commonly used preference-based HRQoL index scores provides new and useful information for identifying and interpreting meaningful change (or differences) in scores.

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MEASURING POPULATION HEALTH STATUS USING EQ-5D: RESULTS FROM THE HEALTH SURVEY FOR ENGLAND 1996–2006

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OBJECTIVES: The development of national health policies requires a clear understanding about how objective and subjective measures of health status vary over time. This task is only possible when generic self-reported instruments are considered part of population surveys alongside traditional health indicators. This study examines variations in self-reported health status in England as measured by the EuroQol EQ-5D